

at least one remote computer,

wherein the remote computer obtains data representing the electroencephalogram (EEG) of the patient, packages and compresses the EEG data into a data file, and transmits the data file; and

at least one central computer connected to the remote computer for file transfer and a database of QEEG features derived from a population patients whose medication outcomes and treatments are known,

wherein the central computer receives the EEG data file transmitted from the remote computer, determines quantitative EEG (QEEG) features of the patient from the data file, processes the QEEG features in dependence on the database by a method comprising the method of claim 9, and returns a report of the predicted likelihoods of response of the patient to medication.

19. A method of treating a patient with a behaviorally-diagnosed psychiatric condition comprising administering a medication to which the patient is predicted to be likely to respond according to a method comprising the method of claim 9.

REMARKS

The present application continues application serial no. 09/148,591, by Suffin and Emory, filed on September 4, 1998, and titled "EEG PREDICTION METHOD FOR MEDICATION RESPONSE."

The Substitute Specification

Replacement of the specification as filed with the substitute specification, including new Fig. 1, enclosed herewith is respectfully requested. The substitute specification corrects numerous informalities in the specification as filed, from which it differs primarily in the following ways: the Abstract has been moved after the claims; a Field of the Invention has been added with text that combines claims 1 and 2 as filed; a copy of the claims as filed has been inserted at the end of the Summary of the Invention; Fig. 1 and a Brief Description of the Figures have been added; references to proprietary materials have been deleted. All changed material in the substitute specification derives directly from the specification as

filed. In particular, Fig. 1 and its description include five steps which literally illustrate elements 1-10 set forth in the Detailed Description of the Invention. All differences between the substitute specification and the specification as filed are indicated in the marked-up substitute specification also enclosed herewith pursuant to 37 C.F.R. § 1.121(b)(3).

Furthermore, pursuant to 37 C.F.R. § 1.125(b)(1), the undersigned states that the substitute specification has been derived entirely from the specification as filed and therefore includes no new matter.

The New Claims

Cancellation of all claims as filed, claims 1-8, and entry of new claims 9-19 is respectfully requested. The new claims are submitted to contain no new matter and are fully supported by, *inter alia*, the portions of the specification cited in the following Table I.

TABLE I

CLAIM	DESCRIPTIVE SUPPORT (in substitute specification)
9, 14	Page 1, lines 31-35; Page 6, lines 1-8
10	Page 8, line 12-13
11	Page 5, lines 28-32
12, 15	Page 6, line 10 to page 7, line 23
13	Page 1, line 35 to page 2, line 4
16, 17	Page 8, lines 8-11
18	Page 3, lines 24-26; page 4, lines 17-30; page 5, line 4; page 7, lines 25-28; page 8, lines 1-3
19	Page 8, lines 8-13

The New Claims Are Allowable

It is respectfully submitted that all the new claims are allowable over the prior art of record in the parent application, because, *inter alia*, this art does not disclose or suggest the use of multivariables that are a combinations of a plurality of QEEG features to predict the likelihood of medication response. Specifically, the prior discloses use of only a single QEEG

feature, while the new claims all recite use of multivariable, composed of multiple QEEG feature, to better predict medication responsiveness.

Moreover, the Examiner is respectfully urged to take fully into account that this application correctly claims all benefits of the prior provisional application 60/058,052, filed September 6, 1997 by the inventors of the present application.

CONCLUSION

The Applicants respectfully request entry of the foregoing amendments and remarks into the file of the above-captioned application. The Applicants believe that all the pending claims are in condition for allowance, and their allowance is respectfully requested.

No fee is believed due with this preliminary amendment; please charge any fee deemed necessary, or credit any overpayment to Pennie & Edmonds deposit account no. 16-1150.

If any outstanding issues remain, the Examiner is invited to telephone the undersigned to discuss the same and to arrange for prompt and efficient handling of the above-captioned application.

Respectfully submitted,

Date

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EXHIBIT A
MARKED VERSION OF THE CLAIMS

9. (New) A method for predicting the likelihood of response to medication of a patient with a behaviorally-diagnosed psychiatric condition comprising:

identifying patterns in a database of quantitative electroencephalographic (QEEG) features derived from a population of patients whose medication outcomes and treatments are known, wherein the patterns are associated with likelihoods of response to a medication, or to a class of medications, or to a combination of medications or classes of medications and are represented by variables comprising multivariables that are composed of two or more QEEG features, and

comparison of patterns of QEEG features of the patient with the identified patterns in the database so that likelihoods of response of the patient to a medication, or to a class of medications, or to a combination of medications or classes of medications associated with the patterns are predicted.

10. (New) The method of claim 9 wherein the database is updated with the QEEG features and the medication outcome of the patient.

11. (New) The method of claim 9 wherein the QEEG features include measures of absolute power, or measures of relative power, or measures of coherence, or measures of symmetry, or measures of the mean frequency in the delta, theta, alpha, and beta bands, wherein the measures are for each of a plurality of EEG electrodes.

12. (New) The method of claim 9 wherein the multivariables include one or more of the following:

(i) coherence interhemispheric, frequency monopolar, or relative power monopolar as measured at a plurality of locations and frequency bands, including anterior delta, posterior delta, anterior theta, posterior theta, anterior alpha, posterior alpha, anterior beta, or posterior beta,

(ii) asymmetry bipolar interhemispheric, asymmetry monopolar interhemispheric, or coherence interhemispheric bipolar as measured at a plurality of frequency bands, including delta, theta, alpha, beta,

(iii) asymmetry intrahemispheric, relative power bipolar, or coherence intrahemispheric as measured at a plurality of combinations of frequency band and location, including delta-left, delta-right, theta-left, theta-right, alpha-left, alpha-right, beta-left, beta-right.

13. (New) The method of claim 9 wherein the classes of medications include psychostimulant class medications, or antidepressant class medications, or anticonvulsant class medications, and wherein the combinations of classes includes combinations of psychostimulant and antidepressant class medications, or combinations of anticonvulsant and antidepressant class medications, or combinations of psychostimulant, antidepressant, and anticonvulsant class medications

14. (New) A method for predicting the likelihood of response to medication of a patient with a behaviorally-diagnosed psychiatric condition comprising:

classifying by rule-based methods patterns of QEEG features of the patient so that likelihoods of response of the patient to a medication, or to a class of medications, or to a combination of medications or classes of medications associated with the patterns are predicted,

wherein the step of classifying uses patterns represented by variables comprising multivariables that are composed of two or more QEEG features, the patterns being identified in a database of quantitative electroencephalographic (QEEG) features derived from a population of patients whose medication outcomes and treatments are known, wherein the patterns are associated with likelihoods of response to a medication, or to a class of medications, or to a combination of medications or classes of medications.

15. (New) The method of claim 14 wherein the multivariables include one or more of the following:

(i) coherence interhemispheric, frequency monopolar, or relative power monopolar as measured at a plurality of locations and frequency bands, including anterior delta, posterior delta, anterior theta, posterior theta, anterior alpha, posterior alpha, anterior beta, or posterior beta,

(ii) asymmetry bipolar interhemispheric, asymmetry monopolar interhemispheric, or coherence interhemispheric bipolar as measured at a plurality of frequency bands, including delta, theta, alpha, beta,

(iii) asymmetry intrahemispheric, relative power bipolar, or coherence intrahemispheric as measured at a plurality of combinations of frequency band and location, including delta-left, delta-right, theta-left, theta-right, alpha-left, alpha-right, beta-left, beta-right.

16. (New) A method for tracking changes produced by the administration of a medication to a patient with a behaviorally-diagnosed psychiatric condition comprising:

obtaining QEEG data from the patient before administration of the medication,
administration of the medication, and

obtaining QEEG data and a clinical improvement score from the patient after
administration of the medication,

17. (New) The method of claim 14 further comprising:

comparison of patterns of QEEG features of the patient before and after
administration of the medication with identified patterns in the database of quantitative
electroencephalographic (QEEG) features derived from a population of patients whose
medication outcomes and treatments are known, wherein the identified patterns are
represented by multivariables composed of two or more QEEG features and are associated
with likelihoods of response to a medication, or to a class of medications, or to a combination
of medications or classes of medications.

18. (New) A computer system for predicting the response of a patient with a behaviorally-
diagnosed psychiatric condition to medication comprising:

at least one remote computer site comprising a computer,

wherein the computer obtains a file representing the QEEG of a patient,
packages and compresses the QEEG data file, and transmits the file; and

at least one central computer site comprising a computer and a database a database of QEEG features derived from a population patients whose medication outcomes and treatments are known,

wherein the computer and database receive an EEG data file transmitted from the remote site, process the EEG data file by a method comprising the method of claim 9, and return a report of the predicted likelihoods of response of the patient to medication.

19. A method of treating a patient with a behaviorally-diagnosed psychiatric condition comprising administering a medication selected by a method comprising the method of claim 9.

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United States Patent
SUFFIN, et al.

**METHOD FOR PREDICTION OF PATIENT RESPONSE TO MEDICATION IN
PSYCHIATRIC DISORDERS**

5 **EEG PREDICTION METHOD FOR MEDICATION RESPONSE**

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08/15/01

CROSS REFERENCE TO RELATED APPLICATIONS

- 10 This is an application based on claims benefit of provisional application number
60/058,052, filed 09/06/97, and is a continuation of application no. 09/148,591, filed
September 4, 1998, the entire texts of which are incorporated herein by reference for all
purposes.

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References Cited

U.S. PATENT DOCUMENTS

5,730,146 3/1998 Itil, et al.
5,083,571 1/1992 Pritchep

ABSTRACT

- The inventors have developed and implemented a unique method for computerized
analysis of an individual patient's electroencephalogram (EEG) recorded by electrodes
20 placed on the scalp, for the purpose of predicting patient response to administration of
medications and therapeutic agents commonly used in psychiatric practice. The business
entity offering this technology commercially is NuPharm Database, LLC.
— The prediction of the nature of responses to medications (adverse, no effect,
favorable outcome) is an important problem in the clinical practice of psychiatry. A growing
number of therapeutic agents are available to the clinician but these agents generate variable
responses when prescribed based solely on the patient's history and current symptoms. The
inventor's technology is used by physicians to improve patient outcome by selecting agents
25 most likely to be effective for a given patient, using a standardized analysis of the digitized
EEG and comparison of individual patient EEG data to a particular database of similar
patients whose clinical outcome to pharmacotherapy is known. The patient is required to be
medication free at the time of the recording.

FIELD OF THE INVENTION

- 30 The field of this invention relates to systems and methods for transmitting digital
EEG data and associated patient identifying information from a remote site to a central site,
and for returning a report summarizing results of analyses and database comparison of the
transmitted EEG, wherein the methods further comprise identifying a set of univariate and
multivariate EEG features that when observed in a patient's EEG can be used to predict a
35 favorable clinical responsive to psychoactive class medications.

EEG PREDICTION METHOD FOR MEDICATION RESPONSE

CROSS REFERENCE TO RELATED APPLICATIONS

5 This application claims benefit of provisional application number 60/058,052, filed 09/06/97, and is a continuation of application no. 09/148,591, filed September 4, 1998, the entire texts of which are incorporated herein by reference for all purposes.

FIELD OF THE INVENTION

10 The field of this invention relates to systems and methods for transmitting digital EEG data and associated patient identifying information from a remote site to a central site, and for returning a report summarizing results of analyses and database comparison of the transmitted EEG, wherein the methods further comprise identifying a set of univariate and multivariate EEG features that when observed in a patient's EEG can be used to predict a
15 favorable clinical responsive to psychoactive class medications.

SUMMARY OF THE INVENTION

 The methodology developed by the inventors, involves recording the EEG in a digital format from a patient diagnosed with a psychiatric disorder, the packaging and
20 transmittal of the computer file containing the EEG and patient information to a report processing center via the Internet, generation of a probabilistically based medication responsivity report, and the return transmission of the report to the recording site via the Internet. EEG signals contained in computer files are not transmitted in real time but rather following the recording, "off-line".

25 The present invention includes a system for compressing, encrypting, tracking, and securely transmitting digital EEG data and associated patient identifying information from a remote site to a processing center, analyzing the EEG data with reference to a database of symptomatic individuals with known treatment outcomes in order to obtain therapy recommendations, and electronically returning a report summarizing results of analyses and
30 database comparison all without requiring telephonic transmission.

 In one embodiment, the analysis methods of the present invention use an identified set of univariate and multivariate EEG features that when observed in a patient diagnosed with a psychiatric disorder, can be used with as part of rule-based classifier or selection method to predict a favorable clinical responses to individual medications and to various
35 classes and combinations of medications, such as psychostimulant class medications,

SUMMARY OF THE INVENTION

The methodology developed by the inventors, involves recording the EEG in a digital format from a patient diagnosed with a psychiatric disorder, the packaging and transmittal of the computer file containing the EEG and patient information to a report
5 processing center via the Internet, generation of a proprietary, probabilistically based medication responsivity report, and the return transmission of the report to the recording site via the Internet. EEG signals contained in computer files are not transmitted in real time but rather following the recording, "off-line".

The present invention includes a system for compressing, encrypting, tracking, and
10 securely transmitting digital EEG data and associated patient identifying information from a remote site to a processing center, analyzing the EEG data with reference to a database of symptomatic individuals with known treatment outcomes in order to obtain therapy recommendations, and electronically returning a report summarizing results of analyses and database comparison all without requiring telephonic transmission.

15 In one embodiment, the analysis methods of the present invention use an identified set of univariate and multivariate EEG features that when observed in a patient diagnosed with a psychiatric disorder, can be used with as part of rule-based classifier or selection method to predict a favorable clinical responses to individual medications and to various classes and combinations of medications, such as psychostimulant class medications,
20 antidepressant class medications, anticonvulsant class medications, combinations of psychostimulant and antidepressant class medications, combinations of anticonvulsant and antidepressant class medications, combinations of psychostimulant, antidepressant, and anticonvulsant class medications.

The present invention also includes a method for computerized generation of clinical
25 reports that integrates interpretive information from medical professionals with results of medication responsivity evaluation.

BRIEF DESCRIPTION OF THE FIGURES

The present invention may be understood more fully by reference to the
30 following detailed description of the preferred embodiment of the present invention, illustrative examples of specific embodiments of the invention and the appended figures in which Fig. 1 illustrates a method of the present invention where: step 1 of Fig. 1 corresponds to elements 1 and 2 of the invention described below; step 2 corresponds to elements 3, 4, and 3; step 3 to elements 6 and 7; step 4 to element 8; and step 5 to elements
35 9 and 10.

DETAILED DESCRIPTION OF THE INVENTION

More specifically, the following steps are employed:

- 1) The EEG is recorded using electrodes placed on the patient's scalp, and the EEG
5 data is stored in a digital format using a standardized protocol available on one of a number
of commercially available instruments (current manufacturers include Cadwell Laboratories,
Bio-Logic Systems Corp., Nicolet Biomedical, Oxford Instruments, among others). The
International 10-20 System convention is used for determining the location of electrodes
placed on the scalp. It is the responsibility of the recording facility to collect data in
10 accordance with the NuPharm Database procedural specifications.
- 2) The following patient criteria apply:
 - a) Patient must have received a psychiatric diagnosis as specified in the
Diagnostic and Statistical Manual, currently the Fourth Edition (DSM-IV).
 - 15 b) Ages between six and ninety.
 - c) Patient is taking no medications. All medications potentially influence the
EEG and must be discontinued or avoided for seven half-lives prior to baseline EBG
examination. This includes "over the counter" sleeping pills, pain medication,
nutritional health supplements and mega-vitamins. ~~A reference list of the most~~
20 ~~commonly used medications and associated half-lives is available from the NuPharm~~
~~Database Report Processing Center.~~
 - d) Insulin, thyroid, estrogen, progesterone and other hormone replacement
agents are not excluded. Some cardiac agents are included in the reference
population of after the age of fifty-five. ~~Further information about use of these~~
25 ~~agents is available from the NuPharm Database Report Processing Center.~~
 - e) Patients with any of the characteristics listed below are not suitable for
prediction of medication responsivity based on EEG analysis:
 - (i) intramuscular depo-neuroleptic therapy within the preceding twelve
months
 - 30 (ii) a history of craniotomy with or without metal prostheses
 - (iii) a history of cerebrovascular accident
 - (iv) spikes or extreme low voltage on the conventional EEG
 - (v) a current diagnosis of seizure disorder
 - (vi) a diagnosis of dementia
 - 35 (vii) mental retardation

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(viii) current use of marijuana, cocaine, hallucinogens or other drugs of abuse

(ix) inability to remain medication-free and drug-free for seven half-lives of the current agent(s) prior to EEG recording

(x) significant abnormality of the CBC, chemistry or thyroid panel with TSH until corrected

f) A "positive" Urine Drug Screen (UDS) interferes with medication prediction methods. Studies are processed only if the UDS is negative just prior to recording the digital EEG.

3) The digital EEG data computer file is packaged along with additional patient identifying information using ~~proprietary NuPharm Database LLC~~ packaging and transmission software currently called "Site Commander". The patient information includes:

a) name

b) date of birth

c) referring physician

d) handedness

e) height

f) weight

g) date of test

h) patient ID (social security number)

Packaging refers to compression of the computer file and encryption of the file so that it cannot be opened or examined by anyone other than at the ~~NuPharm Database~~ processing center. The data transfer is rigorously secured to protect the confidentiality of patient records. The EEG files are encrypted at the recording facility with a key known only to ~~NuPharm Database LLC~~ processing center. The patient ID is transformed using a ~~proprietary~~ algorithm so that even in the case of mail routing error there is no way to associate the data with an individual. The data is compressed and protected with an additional password and data files are transmitted to a secure site. These steps mean that the patient data are protected against even purposeful attempts to intercept and read them.

The transmittal of the EEG file and related patient information is tracked as it is packaged, sent, processed, and returned. All log entries include dates and times calibrated to GMT. ~~This system is Y2K compliant.~~

The computer operating system ~~required~~ preferred to run the ~~proprietary NuPharm Database EEG and~~ packaging and report transmission software is currently Microsoft

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Windows 95/98: The following hardware and software is required to run the Site Commander program preferred:

Hardware Requirements

- 5 Operating System: Windows 95 or Windows 98
- Processor: 486, 133 MHZ.
- Monitor and Video Card capable of displaying 256 colors.
- Disk Space: 35 MB
- RAM: 16MB
- 10 CD-ROM Drive if installing from CD-ROM
- Modem: 33.6 KBaud
- Internet Connection with approved Internet Service Provider

Software Requirements

- 15 Adobe Acrobat Reader Version 3.01 (~~included on distribution CD-ROM~~)
- Microsoft Internet Explorer 4.0 or above (~~included on distribution CD-ROM~~)
- Site Commander Software from NuPharm DataBase LLC (~~included on distribution CDROM~~) The packaging and transmission software
- 20 4) The computer file is transferred off-hours using standard commercially available file transfer protocols (FTP) via the Internet, to a designated processing site administered by NuPharm Database. A special feature of the Site Commander packaging and transmission software exists to allow immediate transfer of files for priority reporting if requested by the client. NuPharm Database The processing site monitors the transfer site in order to detect
- 25 the arrival of new computer files. When a new file is received, it is forwarded to the NuPharm Database Reporting Center for professional interpretation, if requested, and specialized report generation.
- 5) The file is decompressed and decrypted at the NuPharm Reporting Center processing
- 30 site. Experienced technical and professional personnel then review the EEG signals and sections of the recording identified as containing signals generated by extracerebral sources are deleted from subsequent analyses. The samples of EEG selected for inclusion in analysis are then passed to the first stage of analysis.

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6) The first stage of analysis includes computations that extract a standard set of features from the EEG. Quantitative spectral analysis provides commonly used measures of EEG power and relative power. Power is the square of amplitude; amplitude units are in microvolts (μV), power units are microvolts squared (μV^2). Relative power is a measure of
5 the proportion of power in a given frequency band compared to the total band power at a given electrode. Frequency bands are defined as delta, .5 - 2.5 Hz.; theta, 2.5 - 7.5 Hz.; alpha, 7.5 - 12.5 Hz., and beta, 12.5 - 32Hz. The total band is .5 to 32 Hz.

EEG coherence, a commonly used measure of the similarity of activity for a pair of two scalp electrodes, also is extracted by spectral analysis for all interhemispheric and
10 intrahemispheric sets of electrode pairs, for each frequency band as defined above.

Commonly used measures of peak frequency within each defined frequency band are computed.

Combinations of power and coherence measures over defined sets of scalp electrodes are also computed.

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7) Features extracted from individual EEG data by quantitative spectral and statistical analysis are further compared to two distinct databases. In the second stage of analysis, Z-scores representing deviations from a nonsymptomatic reference population are computed. This reference population, often referred to as the "Neurometric" database, contains 2082
20 quantitative EEG measures including absolute power, relative power, coherence, symmetry, and mean frequency of the delta, theta, alpha and beta frequency bands of the EEG at every electrode position of the International 10-20 System for individuals from 6 to 92 years (database #1). The z-score value obtained by comparison of individual's data to the age appropriate subset of the database represents the patient's statistical deviation from the
25 reference database.

8) The third stage of processing involves medication response prediction using the patient database ~~compiled by NuPharm Database LLC~~ (database #2). This prediction is made by first identifying the pattern of EEG deviations from the reference database.
30 Individual patient deviation is then compared with the characteristic features of the population of patients whose medications and treatment outcomes are known. A **proprietary** rule-based classifier is applied to estimate the likelihood that a patient EEG contains a pattern known to be responsive to a given agent, class of agents, or combination of agents or classes of agents. The EEG variables currently used by the classifier are shown in Tables 1-
35 4, below.

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	Column Heading	Description of Abbreviation	Column Heading	Description of Abbreviation
	Table 1		Table 2	
5	RMAD	Relative power monopolar anterior delta	FMAD	Frequency monopolar anterior delta
	RMPD	posterior data	FMPD	posterior delta
	RMAT	anterior theta	FMAT	anterior theta
	RMPT	posterior theta	FMPT	posterior theta
10	RMAA	Anterior alpha	FMAA	anterior alpha
	RMPA	Posterior alpha	FMPA	posterior alpha
	RMAB	Anterior beta	FMAB	anterior beta
	RMPB	posterior beta	FMPB	posterior beta
15	CEAD	Coherence interhemispheric anterior delta	AADL	Asymmetry intrahemispheric delta - left
	CEPD	Posterior delta	AADR	delta - right
	CEAT	anterior theta	AATL	theta - left
	CEPT	posterior theta	AATR	theta - right
20	CEAA	anterior alpha	AAAL	alpha - left
	CEPA	Posterior alpha	AAAR	alpha - right
	CEAB	Anterior beta	AABL	beta - left
	CEPB	posterior beta	AABR	beta - right

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	Table 3		Table 4	
	AED	Asymmetry monopolar interhemispheric delta	CEBD	Coherence interhemispheric bipolar delta
30	AET	Theta	CEBT	Theta
	AEA	Alpha	CEBA	Alpha
	AEB	Beta	CEBB	Beta
	AEBD	Asymmetry bipolar interhemispheric delta	RBDL	Relative power bipolar delta left
35	AEBT	Theta	RBDR	Delta - right

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	AEBA	Alpha	RBTL	Theta - left
	AEBB	Beta	RBTR	Theta - right
5	CADL	Coherence intrahemispheric delta - left	RBAL	Alpha - left
	CADR	Delta - right	RBAR	Alpha - right
	CATL	Theta - left	RBBL	Beta - left
	CATR	Theta - right	RBBR	Beta - right
10	CAAL	Alpha - left		
	CAAR	Alpha - right		
	CABL	Beta - left		
	CABR	Beta - right		

15 9) A formal report for the referring clinician is generated. The report is returned in a format that cannot be modified by the client (Adobe Systems, Inc., "portable document format", or "PDF"). This report contains certain elements as specifically requested by the referring clinician. These elements may include a professional medical interpretation of the digital EEG tracing, a presentation of selected features extracted by quantitative EEG analysis, a presentation of deviations from the Neurometric database, and a statement of the likelihood of favorable pharmacotherapeutic outcome based on comparison with patients having similar EEG features in the NuPharm Database patient database #2. The treating physician is responsible for any medication selection, titrating of dosage and monitoring the patient for side effects and is instructed to incorporate results of reports with the psychiatric assessment to develop into an overall clinical treatment plan.

10) The report is returned ~~to the transfer site administered by NuPharm Database~~ and may be downloaded by the client on a regular schedule, using ~~proprietary NuPharm Database~~ the packaging and transmission software, ~~Site Commander~~, for viewing and printing the report by the client at the recording site. PDF files are opened and displayed using an interface to Adobe Acrobat Reader (TM) software. Reports may be printed on any operating system compatible printer.

11) Follow up EEG recordings can then be used to track changes produced by administration of medications by repeating the entire process outlined above. For follow up

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studies, the patient also is interviewed by the treating physician and Clinical Global Improvement (CGI) is scored. A score of -1 indicates an adverse effect, 0 no improvement, 1 minimal or mild improvement, 2 moderate improvement, and 3 marked improvement or remission of symptoms. The CGI scores are sent to the NuPharm Database analysis
5 processing center and are reported along with changes, expressed as difference scores, on variables shown in Tables 1-4 above.

The invention described and claimed herein is not to be limited in scope by the preferred embodiments herein disclosed, since these embodiments are intended as
10 illustrations of several aspects of the invention. Any equivalent embodiments are intended to be within the scope of this invention. Indeed, various modifications of the invention in addition to those shown and described herein will become apparent to those skilled in the art from the foregoing description. Such modifications are also intended to fall within the scope of the appended claims.

15 The entire disclosures of references cited herein are incorporated herein, in their entireties, for all purposes.

Citation or identification of a reference in this application or in connection with this application shall not be construed that such reference is available as prior art to the present
20 invention.

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WE CLAIM:

1. A unique system for compressing, encrypting, tracking, and securely transmitting digital EEG data and associated patient identifying information via the Internet from a remote site
5 to a Report Processing Center, and including the electronic return of a report summarizing results of proprietary analyses and database comparison all without requiring telephonic transmission.
2. Identification of a set of univariate and multivariate EEG features that when observed in
10 a patient diagnosed with a psychiatric disorder, can be used with NuPharm Database's particular rule-based classifier to predict a favorable clinical responsive to psychostimulant class medications.
3. Identification of a set of univariate and multivariate EEG features that when observed in
15 a patient diagnosed with a psychiatric disorder, can be used with NuPharm Database's particular rule-based classifier to predict a favorable clinical responsive to antidepressant class medications.
4. Identification of a set of univariate and multivariate EEG features that when observed in
20 a patient diagnosed with a psychiatric disorder, can be used with NuPharm Database's particular rule-based classifier to predict a favorable clinical response to anticonvulsant class medications.
5. Identification of a set of univariate and multivariate EEG features that when observed in
25 a patient diagnosed with a psychiatric disorder, can be used with NuPharm Database's particular rule-based classifier to predict a favorable clinical responsive to a combination of psychostimulant and antidepressant class medications.
6. Identification of a set of univariate and multivariate EEG features that when observed in
30 a patient diagnosed with a psychiatric disorder, can be used with NuPharm Database's particular rule-based classifier to predict a favorable clinical responsive to a combination of anticonvulsant and antidepressant class medications.
7. Identification of a set of univariate and multivariate EEG features that when observed in
35 a patient diagnosed with a psychiatric disorder, can be used with NuPharm Database's

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particular rule-based classifier to predict a favorable clinical response to a combination of psychostimulant, antidepressant, and anticonvulsant class medications.

8. A method for computerized generation of clinical reports that integrates interpretive
5 information from medical professionals with results of medication responsivity evaluation according to claim 2.

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ABSTRACT

The present invention includes a system and method for computerized analysis of a patient's electroencephalogram (EEG) recorded by electrodes placed on the scalp, for the purpose of predicting patient response to medications and therapeutic agents commonly
5 used in psychiatric practice. The prediction of the responses to medications (adverse, no effect, favorable outcome) is an important problem in the clinical practice of psychiatry. A growing number of therapeutic agents are available to the clinician but these agents generate variable responses when prescribed based solely on the patient's history and current
10 symptoms. The present invention is used by physicians to improve patient outcome by selecting agents most likely to be effective for a given patient, using a standardized analysis of the digitized EEG and comparison of individual patient EEG data to a particular database of similar patients whose clinical outcome to pharmacotherapy is known.

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